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09/889,737	07/20/2001	Jonathan Gressel	01/22288	8906

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EXAMINER

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ART UNIT	PAPER NUMBER
1638	9

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/889,737	Gessel
	Examiner	Group Art Unit
	FOX	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

— 3 —

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 10/3/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1 - 13 is/are pending in the application.

Of the above claim(s) 1-4 and 12-13 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 5-11 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

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Applicant's election without traverse of Group IV in Paper No. 8 is acknowledged.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-6 and dependents are indefinite in their recitation of "somewhat valuable" which is unduly narrative and imprecise, fails to adequately set forth the degree or amount of value, and thus fails to adequately define the trait or gene conferring it.

Claims 7-11 are indefinite in their recitation of "method or construct according to claims 5 or 6" as it is confusing to depend upon two different statutory classes of invention, namely processes and products, in the same claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring traits which are deleterious to weeds, including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or non-flowering. The claims are also drawn to methods of using these constructs to transform plants.

In contrast, the specification provides no guidance regarding the isolation of any protein (or other gene product) from any source or of any sequence which could confer any of the above traits. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or gene products.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to

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adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to constructs comprising a multitude of genes of a multitude of sequences and from a multitude of sources, encoding proteins (or other products such as antisense RNA or ribozymes) of a multitude of sequences and from a multitude of sources, conferring traits which are innocuous to crop plants but deleterious to weeds, including abolished secondary dormancy, uniform or delayed ripening, anti-shattering, dwarfism, seed stalk bolting, seed coat defects facilitating uniform germination, root storage promotion, biennial growth, or

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non-flowering. The claims are also drawn to methods of using these constructs to transform a multitude of plants of a multitude of species, to obtain a multitude of deleterious phenotypes in a multitude of weedy species and a multitude of innocuous or beneficial phenotypes in a multitude of crop species.

In contrast, the specification provides no guidance regarding the isolation of any protein (or other product) from any source or of any sequence which could confer any of the above traits. Furthermore, no guidance is presented in the specification regarding the isolation or characterization of any gene encoding any of the above putative proteins or other gene products. No guidance is presented regarding crop plant transformation and the evaluation of the putative genes to confer traits which are “innocuous or somewhat valuable” to the crops. Finally, no guidance is provided regarding the identification of any weedy species or transformation therewith to confer a deleterious trait thereto.

The claimed process is hampered by the lack of currently available isolated genes which encode any or all of the proteins involved in the pathways responsible for traits deleterious to weeds (or which modify traits in a manner which would be deleterious), such as secondary dormancy, seed shattering and bolting (see, e.g., Gressel, page 365, column 1, top and fourth paragraphs, and paragraph bridging the columns).

Furthermore, what constitutes a “weed” is variable and crop-species dependent, as well as temporally-dependent. For example, Desplanque et al teach that plants of the cultivated beet species may be considered “weeds” when they are volunteers which have resulted from seed left

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in the field the previous season, which arose from mutations in the crop species which facilitated bolting (see, e.g., page 562, column 1 and paragraph bridging the columns).

In addition, what constitutes a trait which is deleterious to a weed (or which is innocuous or valuable to a crop species) will depend upon the particular crop plant species and the particular weed species, as well as fluctuating environmental stressors. Desplanque et al teach that bolting, rather than being deleterious as claimed in claim 11, is an attractive trait for weed beets and their wild relatives, since it facilitates seed propagation and introgression of valuable agronomic traits such as herbicide resistance into the weeds (see, e.g., page 566, column 2, third full paragraph; page 567, Figure 2 and column 2; page 568, column 1, top two paragraphs). Bartsch et al teach that the gene encoding the BNYVV coat protein is beneficial to the sugar beet crop species in the presence of high levels BNYVV infection, but deleterious to the crop species in the presence of low viral infection levels (see, e.g., pages 143-144; page 146, column 1, first full paragraph).

Modification of “deleterious” traits, such as seed coat-influenced uniform germination, is unpredictable, given the lack of understanding of the inheritance of such traits. Linder teaches that the weedy trait of non-uniform germination, thought to be seed coat-influenced and thus maternally inherited, was not maternally transmitted by the weedy *Brassica rapa* when used as the female parent (see, e.g., page 1181, column 2, first full paragraph; page 1183, column 2, second full and bottom paragraphs; page 1186, column 2, first full paragraph; paragraph bridging pages 1189 and 1191). This unpredictable result was also observed by Landbo et al in the weed

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Brassica campestris (see, e.g., page 212, Table 2; page 213, paragraph bridging the columns, column 2, first and second full paragraphs; page 214, column 2, first full paragraph).

Measurement of “deleterious” traits is also unpredictable, given the effects of environment on their expression, and the possible failure of workers to evaluate plants under these conditions; and given the different expression of transgenes in different genetic backgrounds (see, e.g., Linder, page 1193, column 2, bottom paragraph).

Genetic modification of traits such as seed shattering is unpredictable, due to low heritability, high environmental influence, and the effects of transformation itself. Young teaches that seed shattering in Kleingrass is not highly heritable (see, e.g., page 1156, Abstract). Thus, attempts to either isolate the genes responsible or to modify the seed shattering trait in either the crop species or a wild relative would appear to be difficult. Oard et al teach that seed shattering in cultivated and weedy rice species is highly environmentally influenced, as well as being influenced by the genetic background of the plant, and that the act of transformation with a gene not involved in shattering may still affect the shattering trait (see, e.g., page 14, paragraph bridging the columns, column 2, first full paragraph; page 15, paragraph bridging the columns and Table 1; page 19, column 2, bottom paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate and evaluate a multitude of genes conferring innocuous or valuable traits to a multitude of crop species

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transformed therewith, but conferring deleterious traits to a multitude of weedy species transformed therewith.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 5, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Klee et al (US 5,512,466).

The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait linked to a gene encoding a second trait, which second trait is innocuous to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes delayed ripening.

Klee et al teach tomato plant transformation with a construct comprising a first NPTII gene conferring kanamycin resistance linked to a second gene encoding ACC deaminase which delays ripening (see, e.g., Figures 4-5; column 17, lines 20-60).

Claims 5, 6 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanofsky et al (US 6,198,024 filed April 1998, effectively filed June 1997).

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The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait linked to a gene encoding a second trait, which second trait is innocuous to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes anti-shattering.

Yanofsky et al teach *Arabidopsis* plant transformation with a genetic construct comprising a first kanamycin resistance gene linked to a second AGL8 gene, wherein transformants exhibited delayed or completely inhibited shattering (see, e.g., column 29, line 60 through column 30, line 26), and suggest and claim the transformation of a variety of crop plant species (see, e.g., column 11, lines 7-33 and 44-67; column 12, lines 1-44; claims 1-8 and 17-27).

Claims 5, 6 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaller et al.

The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait linked to a gene encoding a second trait, which second trait is innocuous to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes dwarfism.

Schaller et al teach tobacco transformation with a genetic construct comprising a first gene encoding kanamycin resistance linked to a second gene encoding sterol-C24-methyltransferase, wherein said tobacco plants exhibited dwarfism (see, e.g., page 462; page 463, column 1, top two paragraphs; page 464, paragraph bridging the columns, column 2, first full paragraph; page 465, paragraph bridging the columns and Figure 4).

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Claims 5, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/34088 (COLD SPRING HARBOR).

The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait linked to a gene encoding a second trait, which second trait is innocuous to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes non-flowering.

COLD SPRING HARBOR teach dicot or maize plant transformation with a genetic construct comprising a first gene encoding kanamycin or herbicide resistance linked to a second gene encoding antisense *Id* mRNA, wherein plants with absent flowers were produced (see, e.g., Figures 11A-D; page 7, line 14 through page 8, line 19; page 19, lines 11-19; page 21, line 35 through page 23, line 15; page 27, line 21 through page 28, line 5; page 30, line 22 through page 31, line 29).

Claims 5, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al.

The claims are broadly drawn to a genetic construct comprising a gene encoding a first trait linked to a gene encoding a second trait, which second trait is innocuous to a crop species but deleterious to a weed, and methods for the transformation of crop plants therewith, wherein the second trait includes non-flowering.

Wang et al teach *Arabidopsis* plant transformation with a genetic construct comprising a first gene encoding kanamycin or herbicide resistance linked to a second gene encoding CCA1

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protein, wherein plants with absent flowers (when compared to control plants of the same age) were produced (see, e.g., page 1208, column 2, bottom paragraph; page 1209, Figure 2; paragraph bridging pages 1214 and 1215).

Claim 7 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated gene whose product will abolish secondary dormancy, or plants transformed therewith.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 15, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

